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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,682	10/29/2003	Charles Raymond Degenhardt	9401	7782

27752 7590 05/16/2007
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EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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05/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/696,682

Applicant(s)

DEGENHARDT ET AL.

Examiner

Lezah W. Roberts

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-15 and 17-19 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>A-B</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to the Restriction Requirement and Election of Species

Claims 4-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 16, 2007.

Applicant's election with traverse of 1-hydroxy-2-pyridinethione for an anti-dandruff agent, 1-[3-(2-oxo-octadecanoylamino)-propyl]-pyridinium bromide for a ketoamide surfactant, a guar derivative for a cationic polymer and group I in the reply filed on February 16, 2007 is acknowledged. The traversal is on the ground(s) that the restriction is improper and there would not be undue burden to search the genus represented in the instant claims. In regards to the restriction requirement the groups do not meet the definition of patentably distinct. This is not found persuasive because the claims encompass various species of each category requiring a search for not only the species but also combinations of the species. Especially in regards to claim 1 wherein R_3 is a linking group. This limitation is broad and a proper search would be difficult to conduct without an indication of where to begin. In regards to the anti-dandruff agent, Applicant argues all the agents have similar properties, therefore if one is found it would be obvious to use any one of the recited species of the instant claims. Therefore, this requirement has been withdrawn. In regards to the restriction requirement, the compositions may be used for cleaning hair utensils therefore the compositions do not

Art Unit: 1614

necessarily have to be used for the method recited by group II. Furthermore, if the compositions claims are found patentable the method claims is subject to rejoinder therefore a divisional application would be unnecessary to receive the patent protection of the non-elected invention if the claims of the non-elected invention are in condition for allowance.

The requirement is still deemed proper and is therefore made FINAL.

Claims

Claim Rejections - 35 USC § 112 – Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1) Claims 1, 3, 7-14 and 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

1) The appearance of mere indistinct words in a specification or a claim (here the phrase "linking group"), even an original claim, does not necessarily satisfy the written description requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004). A description of what a material

Art Unit: 1614

does, rather than of what it is, usually does not suffice to provide an adequate written description of the invention. Univ. of Cal. v. Eli Lilly, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when coupled with a known or disclosed correlation between function and structure." Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003). No such correlation has been disclosed here.

The claims recite the limitation "R₃ is a linking unit". The definition may encompass a broad range of functional groups. There is little guidance disclosed by the specification as to what "linking unit" encompasses. The specification does disclose the preferred linking group but does not go further in defining the limits to which the phrase encompass or how one would determine what is a suitable "linking group".

2) The appearance of mere indistinct words in a specification or a claim (here the term "derivative"), even an original claim, does not necessarily satisfy the written description requirement. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004).

Claim 18 recites "guar derivative" but the disclosure does not clearly define what the phrase encompasses. The specification recites, "guar gum derivatives, such as guar hydroxypropyltrimonium chloride, specific examples of which include the Jaguar series

Art Unit: 1614

commercially available from Rhone-Poulenc Incorporated and the N-Hance series commercially available from Aqualon Division of Hercules, Inc.” It gives one specific example of what is encompassed by guar gum derivatives and where these derivatives may be found but does not expand on when a compound is not considered a guar gum derivative.

It is suggested Applicant recite guar gum, which would encompass all the guar gum derivatives.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

Art Unit: 1614

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1, 3, 7-14 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunlop et al. (US 2002/0102228).

Dunlop et al. disclose shampoos providing a superior combination of anti-dandruff efficacy and conditioning. The compositions comprise an anti-dandruff agent such as ketoconazole, pyridinethione salts such as zinc 1-hydroxy-2-pyridinethione, and selenium sulfide (paragraphs 0117 to 0121), encompassing claims 7-9. They comprise about 0.1% to about 4% of the compositions. The particle size of the pyridinethione ranges up to 20 micrometers. The surfactants include anionic surfactants and comprise 5% to about 50% of the compositions. Water comprises from about 20% to about 94.75% of the compositions (paragraph 0170). The compositions optionally comprise hair growth regulating agents. They comprise 0.001% to about 15% of the compositions, encompassing claims 12-14. These agents include ketoamides. The ketomides disclosed in the instant claims are encompassed by the ketomides incorporated by reference from US Provisional Applications 60/102,449 and 60/102,458. Cationic guar components may also be included in the compositions (paragraph 0134). The conditioning agents include silicone conditioning agents incorporated into the

compositions at a concentration of 0.01% to 10% (paragraphs 0045 to 0046), encompassing claim 17. The reference differs from the instant claims insofar as it does not disclose the ketoamides with the formula recited in the instant claims.

The reference is not anticipatory insofar as one must "pick and choose" from different lists of alpha keto amide compounds and anti-dandruff agents. That being said, it would have been obvious in a self-evident manner to have selected structure of the disclosed formula from one list and 1-hydroxy-2-pyridinethione (or one of the other two agents in the instant claims) from another, motivated by the unambiguous disclosure of each individually, and consistent with the basic principle of patent prosecution that a reference should be considered as expansively as is reasonable in determining the full scope of the contents within its four corners.

2) Claims 1-3, 7-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaczvinsky, JR et al. (US 2003/0165449).

Kaczinsky et al. disclose compositions for treating dandruff. The compositions comprise an alpha-keto amide with the recited formula I (structure 3). The compounds are used to inhibit *Malassezia globosa* lipase, which is believed to cause dandruff. Surfactants are included at concentrations ranging from 0.5% to about 20%. Water comprises from about 20% to about 95%. Cationic polymers include guar gum derivatives and have a concentration ranging from 0.05% to 3% (paragraph 00112). Anti-dandruff agents include ketoconazole, pyridinethione salts such as zinc 1-hydroxy-2-pyridinethione, and selenium sulfide (paragraphs 0187 to 0195). The particle size of

Art Unit: 1614

the pyridinethione ranges up to 20 micrometers. Silicone conditioning agents are included and comprise from about 0.01% to about 10% of the compositions. They comprise about 0.1% to about 4% of the compositions. The conditioning agents include silicone conditioning agents incorporated into the compositions at a concentration of 0.01% to 10% (paragraphs 0120 to 0121), encompassing claim 17. The reference differs from the instant claims insofar as it does not disclose an example of all the components in one composition together.

The reference is not anticipatory insofar as one must "pick and choose" from different lists of alpha keto amide compounds and anti-dandruff agents. That being said, it would have been obvious in a self-evident manner to have selected structure 3 from one list and 1-hydroxy-2-pyridinethione (or one of the other two agents in the instant claims) from another, motivated by the unambiguous disclosure of each individually, and consistent with the basic principle of patent prosecution that a reference should be considered as expansively as is reasonable in determining the full scope of the contents within its four corners.

Allowable Subject Matter

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The compound does not appear to be in the prior art.

Claims 1-3, 7-15 and 17-19 are rejected.

Claims 4-6 are withdrawn.

Claim 16 is objected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1614

Lezah Roberts
Patent Examiner
Art Unit 1614

A handwritten signature in cursive script, appearing to read 'Lezah Roberts', written in black ink.

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in cursive script, appearing to read 'Frederick Krass', written in black ink.